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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,229	04/11/2001	Avram Scheiner	279.337US1	2999

21186 7590 03/26/2004

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EXAMINER

DROESCH, KRISTEN L

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/833,229

Applicant(s)

SCHEINER ET AL.

Examiner

Kristen L Droesch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/29/04 (response).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22, 56-65 and 73-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-8, 59-65 and 73-77 is/are allowed.
- 6) ☒ Claim(s) 9-22 and 56-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 April 2001 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 9 objected to because of the following informalities: inconsistency between the use of "external system" and "external device". Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 9-11, 13-16, and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al. (5,792,195) in view of Koestner et al. (5,300,093).

Regarding claims 9, and 20, Carlson et al. shows a first heart sound sensor, (34) a second cardiac electrical signal sensor (24), a third cardiac electrical signal sensor (26), an first interface circuit (42) and a first control circuit (32, 36, 38) that includes a bandpass filter (46), a systole detector, and an ensemble averager (96, 98) (Fig. 2; Col. 6, lines 44 -55; Col. 7, lines 23-58) and an external system (40) with a second interface circuit. Although Carlson et al. fails to show an output device configured to simultaneously output multiple signals; and a second control circuit coupled to the second interface circuit and the output device configured to receive the first, second, and third data and generate control signals causing the output device to simultaneously output at least the first, second and third sensed signals, attention is directed to Koestner et al. which shows an external monitor and display that is coupled telemetrically to an implantable medical device which is configured to receive the first, second, and third data and generate

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control signals causing the output device to simultaneously output at least the first, second and third sensed signals (Col. 27, line 9-Col. 32, line 52). Koestner et al. teaches that the simultaneous transmission and display of electrical signals and physiological signals allows the interrelationships between mechanical and electrical cardiac signals to be set forth quickly and easily and greatly enhances the diagnostic information available to the physician (Col. 32, lines 44-52). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the external system of Carlson et al. with the external system of Koestner et al. in order to quickly and easily set forth the interrelationships between mechanical and electrical cardiac signals and greatly enhance the diagnostic information available to the physician.

Regarding claims 10-11, and 21, Carlson et al. further shows the heart sound sensor is an accelerometer (34) located internal to the implantable housing (10)

With respect to claim 19, Carlson et al. shows the data transmitted is processed data (Col. 4, lines 46-62).

Regarding claim 13, the second sensor includes an EGM sensing electrode (16, 18, 20, 22) and the second signals are representative of EGM electrical signals.

With respect to claims 14-16, and 22, Carlson et al. shows the second sensor (24) includes an atrial sensing electrode (20, 22), and the third sensor (26) includes a ventricular sense electrode (16,18) wherein the second sensor is disposed in the right side of the heart.

Regarding claim 20, Carlson et al. shows a systole detector where detection of systole triggers the ensemble averager (Col. 6, line 40 –Col. 7, line 13).

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4. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al. (5,792,195) in view of Koestner et al. (5,300,093) and further in view of Lekholm (4,763,646). Although Carlson et al. and Koestner et al. disclose the claimed invention except for the heart sound sensor being located externally from the implantable housing, attention is directed Lekholm who teaches that the heart sound detector can be located on a separate line or on an electrode lead. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the sensor as taught by Carlson et al. and Koestner et al. with the sensor of Lekholm, since applicant has not disclosed that this location of the sensor provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any location for the sensor such as the external location taught by Lekholm for detecting heart sounds.

5. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al. (5,792,195) in view of Koestner et al. (5,300,093) and further in view of Tockman et al. (5,540,727). Although Carlson et al. and Koestner et al. disclose the claimed invention except for explicitly teaching the second sensor is located in a left side of a heart, attention is directed to Tockman who shows a similar device with a sensor (27, 29) located in the left side of the heart for sensing ventricular electrical signals (Col. 3, lines 20-28). It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to locate the second sensor of Carlson et al. and Koestner et al. in a left side of a heart, since applicant has not disclosed that this particular location provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any location for the second sensor

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such as the location in a left heart taught by Tockman et al. for sensing left ventricular electrical signals.

6. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al. (5,792,195) in view of Koestner et al. (5,300,093) and further in view of Turcott (6,409,675). Although Carlson et al. and Koestner et al. disclose the claimed invention except for explicitly teaching the transmitted data includes raw data determined by digitizing the sensed signals, attention is directed to Turcott which shows raw data can be recorded by an implantable device and transmitted via telemetry to an external processor (Col. 14, lines 38-48). It would have been obvious to one with ordinary skill in the art at the time the invention was made to transmit raw data rather than processed data because it would be far simpler and the step of processing the data would be omitted. Omission of an element and its function if the function of the element is not desired is generally recognized as being within the level of ordinary skill in the art. In re Kuhle, 526 F.2d 553, 188 USPQ 7 (CCPA 1975).

7. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Turcott (6,409,675) in view of in view of Lekholm (4,763,646) and Tockman et al. (5,540,727).

With respect to claim 56, Turcott shows a method of outputting heart sounds using an implanted system including receiving first data representative of detected heart sounds (Col. 7, lines 37-40), applying control signals to an output device to cause the output device to generate outputs representative of the detected heart sounds (Col. 13, lines 60-65).

Although Turcott fails to show detecting heart sounds using a plurality of implanted heart sound sensors, attention is directed to Lekholm which teaches an implantable device with a plurality of heart sound sensors (22, 23, 24). Lekholm teaches that the plurality of sensors can be

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placed to measure the atrium, or the ventricle, or placed where it can measure both the atrium and ventricle depending on the application and function of the system (Col. 3, line 64-Col. 4, line 9). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Turcott with the method of using a plurality of sound sensors as Lekholm teaches in order to place sensors to measure the atrium, the ventricle, or where the sensor can measure both the atrium and ventricle depending on the application and function of the system.

Although Turcott fails to show generating data representative of heart sounds using ensemble averaging, attention is directed to Tockman et al., which teaches generating data representative of heart sounds using ensemble averaging in order to eliminate transient non-periodic noise (Col. 3, line 66-Col. 4, line 4; Col. 5, lines 49-55). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Turcott. with generating data representative of heart sounds using ensemble averaging as Tockman et al. teaches in order to eliminate transient non-periodic noise.

8. Claims 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turcott (6,409,675) in view of in view of Lekholm (4,763,646) and Tockman et al. (5,540,727) as applied to claim 56, and further in view of Little et al. (4,628,939). Turcott further shows detecting first and second cardiac electrical signals using a second and third implanted sensor and transmitting data representative of the first and second cardiac electrical signals to the external system (Col. 15, lines 35-49). Although Turcott, Lekholm, and Tockman fail to show simultaneously displaying the data representative of the heart sounds and the data representative of the first and second cardiac electrical signals, attention is directed to Little et al. which shows

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displaying an electrocardiogram signal and phonocardiogram signal simultaneously in order to circumvent the inherent subjective difficulty in interpretation of heart sounds (Col. 2, line 64-Col. 3, line 2). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Turcott, Lekholm, and Tockman with simultaneously displaying an electrocardiogram signal and phonocardiogram signal as Little et al. teaches in order to circumvent the inherent subjective difficulty in interpretation of heart sounds.

Response to Arguments

9. Applicant's arguments, see Paper No. 13, pages 12-13, filed 1/29/04, with respect to claims 1-8 have been fully considered and are persuasive. The rejection of claims 1-8 has been withdrawn.

10. Applicant's arguments with respect to claims 9-22 have been considered but are moot in view of the new ground(s) of rejection.

11. Applicant's arguments filed 1/29/04 with respect to claims 56-58 have been fully considered but they are not persuasive.

Applicants assert that they can not find in Turcott a suggestion or motivation to detect heart sound using the plurality of heart sound sensors of Lekholm. The examiner points out that the suggestion or motivation for such a modification does not necessarily have to be found in the base reference itself. The motivation can be found in the secondary reference, as is the case with the motivation for using a plurality of heart sound sensors provided by the Lekholm reference.

Applicants also assert that they can not find in Turcott or Lekholm a suggestion or motivation to generate data representative of hear sounds using ensemble averaging of Tockman

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et al. The examiner points out that the suggestion or motivation for such a modification does not necessarily have to be found in the base reference itself. The motivation can be found in the secondary reference, as is the case with the motivation for generating representative data of heart sounds using ensemble averaging provided by the Tockman et al. reference.

Allowable Subject Matter

12. Claims 1-8, 59-65, 73-77 allowed.

Regarding claims 1-8, and 73-75, the prior art of record fails to teach or suggest an implantable device with a plurality of implantable heart sound sensors and a control circuit with a first and second processing paths, where the first processing path includes a first band pass filter, a rectifier, a low pass filter and a first ensemble averager and the second processing path includes a second band pass filter and a second ensemble averager.

With respect to claims 59-65, and 76-77, the prior art of record fails to teach or suggest a method including generating first data representative of heart sounds *in the implanted system*, receiving the data *from the implanted system*, generating control signals using the first data in combination with generating timing comparison control signals and applying the control signals and the timing comparison control signals to an output device to generate representations of heart sounds and timing information.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mai et al. (6,643,548) shows an implantable device which detects heart sounds and cardiac electrical signals.

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14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kyle Drosel

kld

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3/22/04